

MEDICAL DEVICE RECALL

PCRopsis RVD products & accessories.

Dear Device Customer/Distributor,

The purpose of this letter is to advise you that Entopsis Inc., FL, USA is voluntarily recalling the following PCRopsis RVD products & accessories shipped/received before February 8th 2023 due to misleading label statements on the product label.

The voluntary recall is done at the advice of the Food and Drug Administration (FDA) that the labeling of PCRopsis devices does not accurately reflect the research status of the devices. Therefore, there is a potential risk for improper use of the PCRopsis devices. PCRopsis devices are designed for nucleic acid extraction from a variety of biological samples and do not provide any diagnostic information.

Frequency of failures and complaints:

At this time, we are not aware of any adverse reactions associated with device failure and have not received any complaints related to the performance or quality of PCRopsis devices.

Risk to Health:

Device failure caused due to improper use may affect the downstream applications sought after nucleic acid extraction, for example, nucleic acid detection assays (Polymerase chain reactions or nucleic acid sequencing).

How to recognize that the device may fail? - The assays designed for nucleic acid detection after extraction will not yield the expected results using established samples; for example positive controls used for detection will not yield the proposed results (i.e. positive signal).

Actions to be taken by the Customer/User:

Entopsis Inc., requests that the product lots listed below - shipped/received before February 8th, 2023 be promptly discontinued from use and discarded from inventory as per your non-hazardous waste disposal plan. The labeling of PCRopsis products was revised on February 8th, 2022. Updated statements of intended use and revised instructions for use are available on www.pcropsis.com. If you are currently using or intend to use the PCRopsis product lots affected by this recall please contact us at team@entopsis.net or 1-888-407-5070 (Monday to Friday 9.00 AM to 4.30 PM Eastern Time) to request a replacement. If you are a re-distributor of PCRopsis devices, notify your end customer with a copy of this letter. Please acknowledge the removal of affected product lots by filling out the attached acknowledgment form and returning it to us at team@entopsis.net.

Product and Distribution Information: February 8th, 2023

| Product and Distribution Information Table | | | | | | | |
|--|--|---------------|----------------------------------|---------------------------|------------------------|---------|----|
| Product Names, Unique Device Identifier (if applicable) | Manufacturer's Product Number/Catalog Number | Lot | Manufacturing/Distribution Dates | Expiration Date (MM/YYYY) | Quantity Shipped | | |
| PCRopsis(TM) RVD w/ Enh. (1ml) (25ml) (100ml) | B550783360010 | 18 | Pre February 8th 2023 | 05/2023 | 47 | | |
| | | 20 | | 07/2023 | 236 | | |
| | | 21 | | 07/2023 | 82 | | |
| | B550783360250 | 18 | | 05/2023 | 8 | | |
| | | 20 | | 07/2023 | 21 | | |
| | | 21 | | 07/2023 | 2 | | |
| | B550783361000 | 21 | | 07/2023 | 1 | | |
| | PCRopsis(TM) RVD-RT (1ml) (25ml) (100ml) | B550783780010 | | 4 | Pre February 8th 2023. | 02/2023 | 58 |
| | | | | 7 | | 07/2023 | 35 |
| B550783780250 | | 6 | 06/2023 | 1 | | | |
| B550783781000 | | 7 | 07/2023 | 3 | | | |
| PCRopsis(TM) Support (1ml) (0.25ml) (25ul) | B5507870010 | 4 | Pre February 8th 2023. | 05/2023 | 11 | | |
| | B5507870020 | 4 | | 05/2023 | 43 | | |
| | | 5 | | 07/2023 | 35 | | |
| | B5507870030 | 5 | | 07/2023 | 5 | | |
| PCRopsis(TM) Activator (1.5ml) (0.5ml) | B5502280010 | 3 | Pre February 8th 2023. | 05/2023 | 10 | | |
| | | 4 | | 07/2023 | 1 | | |
| | B5502280020 | 3 | | 05/2023 | 11 | | |
| | | 4 | | 07/2023 | 19 | | |
| | | 5 | | 04/2023 | 11 | | |
| PCRopsis(TM) Lysis Beads (x25) (x25) (x50) (25g) (1000g) | B5505970002 | 2 | Pre February 8th 2023. | 05/2024 | 18 | | |
| | | 3 | | 06/2024 | 5 | | |
| | B5505978252 | 5 | | 06/2024 | 3 | | |
| | | B5505978503 | | 2 | 05/2024 | 3 | |
| | B55059700250 | | | 2 | 05/2024 | 16 | |
| | | 3 | | 06/2024 | 49 | | |
| | | 4 | | 06/2024 | 39 | | |
| | 5 | 06/2024 | | 229 | | | |

| | | | | | |
|------------------------------|--------------|---|---------------------------|---------|---|
| | B55059710000 | 4 | | 06/2024 | 1 |
| PCRopsis BCSNano (1mL) | B5502276001 | 3 | Pre February 8th 2023. | 11/2023 | 3 |
| PCRopsis Buccal (1mL) | B550282001 | 4 | Pre February 8th 2023. | 08/2023 | 6 |

Entopsis Inc., has revised the labeling and instructions of use on February 8th 2023. Updated statements of intended use and instructions of use are available at www.PCRopsis.com.

Contact us at team@entopsis.net or 1-888-407-5070 - Monday to Friday 9.00 AM to 4.30 PM US Eastern Time (GMT -5) with any questions you may have. **Please acknowledge the recall action by filling the online acknowledgement survey form by scanning the QR code.** If you would like to request a replacement for affected lots currently in your use contact us.

Authorized by:

Name: (Print) Obdulio Piloto

Signature: 

Title: CEO



Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

<https://www.surveymonkey.com/r/WB8VPG2>

Scan the code above to complete the required **Acknowledgement and Receipt Form**